

### **Remarks**

By this Office Action, the Examiner has required restriction to one of the following inventions under 35 U.S.C. §§ 121 and 372:

Group I, claims 1-6, the use of sodium chloride formulated coated with an agent.

Group II, claims 7-11, drawn to sodium chloride formulated coated with an agent.

Group III, claims 12-16, drawn to a patch suitable for adherence to skin.

Group IV, claims 17-23, drawn to a device consisting of holding a medically efficacious compound.

Group V, claims 24-34, drawn to a preparation method.

Responsive to the requirement for restriction, Applicant elects, *with traverse*, to prosecute the invention of Group V embraced by the amended claims 24-33 and 7-11 and the newly added claim 35, directed to a preparation containing an agent that forms a liquid impermeable but gas permeable layer.

By way of the instant response, claims 1-6 have been amended to be directed to a method of making a medicament. Claims 7-11 have also been amended to be dependent from the elected claim 30 and hence elected. In addition, claim 35 is added new to be directed to a preparation containing an agent that forms a liquid impermeable but gas permeable layer and hence elected. Support for the amendment is found, *inter alia*, at lines 18-21 on page 6, line 25 on page 16 to line 4 on page 17, at lines 17-19 on page 18 of the specification and in the claims as filed. It is submitted that no new matter is introduced by this response.

Furthermore, claims 1-6 and 34 as directed to a method of making a medicament are submitted to be related to the invention Group V covering claims 24-33, 7-11, and 35 as product and process claims. In the event that the elected invention Group V is found to be allowable, the rejoinder of the non-elected claims 1-6 and 34 is hereby requested under MPEP 821.04(b).

Moreover, claims 12-16 covered under the invention Group III and claims 17-23 covered under the invention Group IV have acquired all the limitation of the elected product claim 7 pursuant to MPEP 821.04(a). In the event the elected product invention Group V covering claims 24-33, 7-11, and 35 to be allowable, the rejoinder of the non-elected claims 12-16 and 17-23 is hereby requested under MPEP 821.04(a).

**Remarks Directed to Lack of Unity of Invention Under 35 U.S.C. § 121 and PCT 13.1**

As stated on page 2 of the Office Action, "the inventions listed as Groups I-V do not relate to a single general inventive concept under 35 U.S.C. § 121 or PCT Rule 13.1 because they lack the same or corresponding special technical features . . . . The sodium chloride formulated coated with an agent of claim 7 does not present a contribution over the prior art since it is described in Herbig et al. (U.S. patent No. 5,798,119, see column 6, lines 51-67). As a result, Group II does not share a special technical feature with the claims of Groups I, III, IV, and V. Therefore, the claims are not so linked by a special feature within the meaning of PCT Rule 13.2 [13.1] so as to form a single inventive concept, and unity between Groups I-V is broken".

For at least the reasons stated below, Applicant respectfully traverses the basis to the instant restriction requirement with particular reference to the cited Herbig et al, hereafter *Herbig*.

Contrary to the above cited assertion stated in the Office Action, *Herbig* relates to "an osmotic device that, following imbibition water vapor, provides for the controlled release of a beneficial agent to a non-aqueous environment" (Abstract). It is particularly worth noting that sodium chloride, taught as an osmagent (col. 6, lines 51-67), is not coated with a layer of an agent that is "liquid impermeable but gas permeable" according to the instant claim 7. Rather, *Herbig* teaches that sodium chloride is present in an environment such as a hydrophilic formulation 2 that is permeable to water, the result of which induces an osmotic pressure differential such that a beneficial agent 3 may be bursted into an non-aqueous environment through emanator pad 6 (Figure 1; col. 8, lines 26-41). As such, *Herbig* does not teach or suggest

the special technical aspect of sodium chloride coated with an agent of claim 7 that is "liquid impermeable".

The Examiner is requested to provide Applicant as to how *Herbig* teaches the amended claim 7 and all the claims dependent therefrom, if the Examiner finds the above observation and remarks to be insufficient for traversal.

It should also be noted that claims 1-34 have been found to fulfil the requirements of unity per Rules 13.1, 13.2 PCT according to International Preliminary Report on Patentability dated Nov. 10, 2005 (sheet 4, item 7).

If there are any questions or concerns as to patentability, the Examiner is invited to telephone the undersigned so that the matter can be promptly handled and the case be passed on to issue.

Please charge any fees or credit any overpayments as a result of the filing of this paper to our Deposit Account No. 02-3978.

Respectfully submitted,

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